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base form. Support for the amendment is found in the Examples, original claims, and page 5, lines 20-24. Claim 6 has been amended to delete salts of the local anesthetic from the Markush group. Claims 1-10 have been further amended for clarity. Claims 11-19 are new claims. Support for Claim 11 is found on page 12, lines 22-23. Support for Claim 12 is found on page 12, line 4. Support for Claim 13 is found on page 13, line 18. Support for Claim 14 is found on page 14, lines 16-17. Support for Claim 15 is found on page 19, line 22-23. Support for Claim 16 is found on page 15, line 2. Support for Claim 17 is found on page 15, lines 3-13. Support for Claim 18 is found on page 16, line 22. Support for Claim 19 is found on page 21, lines 5-16. No new matter is believed to have been added by this amendment.

REQUEST FOR RECONSIDERATION

Applicants thank Examiner Gollamudi and the Examiner's Supervisor Jose Dees for the helpful and courteous discussion of November 1, 2002. During the discussion, Applicants' U.S. representative presented arguments that the presently claimed invention allows the administration of the base forms of local anesthetics over an extended period of time. The Examiner agreed that an amendment to the claims requiring that the local anesthetic be present in its base form would overcome the rejection in view of the Higo reference. Applicants' U.S. representative presented further arguments noting that the presently claimed invention contains an adhesive mass that is non-aqueous in nature. The Examiner indicated that the present claims, which require that the adhesive mass is non-aqueous, are not obvious in view of the Ono patent which requires the presence of water.

Claim 1 has been amended herein to require that the local anesthetic is present in its base form. Applicants note that while the salt form of a local anesthetic such as lidocaine can

be significantly more soluble in water than the parent base form, the salt form is less capable of being absorbed through the skin (page 5, lines 10-24). The Higo patent (U.S. 5,866,157) requires the presence of an organic acid in the adhesive layer. The organic acid is stated to form an ion-pair with the organic acid (column 3, lines 23-26). In fact, Higo claims:

> "a matrix patch formulation which comprises an adhesive layer containing an organic acid, a physiologic active substance comprising a basic drug *which forms an ion-pair with said organic acid* . . ." (italics added; Claim 1).

The Examples of the Higo patent include organic acids such as sodium acetate, sodium salicylate and sodium propionate (Examples 1, 4 and 6). The Higo patent discloses that the physiological active agent forms an ion-pair with an organic acid. Higo is disclosing and claiming an invention different from the presently claimed invention. In the presently claimed invention, the adhesive mass contains a local anesthetic which is required to be present in its base form. In contrast, the Higo patent requires that the physiological active substance is present as an ion-pair (salt) with an organic acid.

Applicants submit that the presently claimed invention, which requires the local anesthetic to be present in its base form, cannot be obvious or anticipated by a reference which discloses a physiological active substance present with an organic acid in the form of an ion-pair.

The Office further rejected the claims in view of a combination of Higo with Ono (U.S. 5,827,529) as obvious under 35 U.S.C. § 103(a). Applicants submit that the present claims cannot be obvious in view of the Ono patent because the Ono patent requires that the drug-containing layer also contain water (see Claim 1 of Ono; column 9, lines 26-27). The present claims require a non-aqueous adhesive mass.

Applicants submit the present invention is not obvious in view of the Higo patent as evidenced by the limitation that the local anesthetic is present in its base form. The presently

claimed invention is further unobvious in view of the prior art cited by the Examine since the present claims require that the adhesive mass is non-aqueous.

Applicants submitted an Information Disclosure Statement containing two references (reported on an International Search Report) provided on a PTO-1449 form. A date-stamped filing receipt evidencing the submission of the IDS on June 4, 2001 is attached herewith. A copy of the PTO-1449 form is also attached for the Examiner's convenience. Applicants respectfully request the Examiner return a signed and initialed copy of the PTO-1449 form with the next communication from the Office.

Applicants submit that all claims are in condition for allowance. Applicants respectfully request the withdrawal of the outstanding rejections and the passage of all now pending claims to Issue.

Respectfully submitted,

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OF AMENDMENT AND REQUEST FOR RECONSIDERATION

IN THE CLAIMS

--1. (Amended) A tape preparation [for transdermal absorption which is characterized by that] comprising an adhesive mass [prepared by incorporating] comprising 1-30 parts by weight of a local anesthetic in a base form [as an active ingredient] in 100 parts by weight of a nonaqueous adhesive mass base comprising 5-50% by weight of a styrene-isoprene-styrene block copolymer, 1-60% by weight of an alicyclic saturated hydrocarbon resin, 5-60% by weight of liquid paraffin and 1-30% by weight of butyl rubber, wherein the adhesive mass is supported on a backing.

2. (Amended) A tape preparation [for transdermal absorption] as claimed in Claim 1, wherein the effect of the local anesthetic lasts for 24 to 72 hours.

3. (Twice Amended) A tape preparation [for transdermal absorption] as claimed in Claim 1 which causes stratum corneum abrasion only to [be] a slight extent even when applied continuously for a long period of time.

4. (Twice Amended) A tape preparation [for transdermal absorption] as claimed in Claim 1 which is excellent in duration of effect on alleviating pains due to herpes zoster or postherpetic neuralgia.

5. (Twice Amended) A tape preparation [for transdermal absorption] as claimed in Claim 1 which is excellent in duration of effect on alleviating pains on the occasion of high frequency therapy or laser therapy, pains upon treatment of liver spots or dark red birthmarks,

pains upon biopsy, pains on the occasion of skin grafting for the treatment of thermal burns, or pains on the occasion of treatment of molluscum contagiosum.

6. (Twice Amended) A tape preparation [for transdermal absorption] as claimed in Claim 1, wherein the local anesthetic is selected from the group consisting of lidocaine, procaine, oxyprocaine, dibucaine, tetracaine, bupivacaine, mepivacaine, and propitocaine[, and salts thereof].

7. (Amended) A tape preparation [for transdermal absorption] as claimed in Claim 1, wherein the local anesthetic is lidocaine.

10. (Amended) A tape preparation [for transdermal absorption] as claimed in Claim 1 which causes stratum corneum abrasion only to a slight extent even when applied continuously for a long period of time, and is excellent in duration of effect on alleviating pains due to herpes zoster or postherpetic neuralgia.

8-9 (Canceled).

11-19. (New).--